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09/995,493	11/28/2001	Martin Handfield	01-662	1452

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/995,493

**Applicant(s)**

HANDFIELD ET AL.

**Examiner**

Padmavathi v. Baskar

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-27, 30-33, 36, 37, 40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 17-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30, 31 and 40 is/are allowed.
- 6) ☒ Claim(s) 32, 33, 36, 37 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) ~~1-14, 17-27~~ <sup>1-14, 17-21</sup> are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/9/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment filed on 5/9/05 has been entered.

#### ***Status of claims***

2. Claims 30, 32, 36 and 40 have been amended.

Claims 15, 16, 28, 29, 34, 35 and 38-39 have been canceled.

Claims 30-31, 32-33, 36- 37, and 40-41 are under examination

Claims 1-14 and 17-27 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected group.

#### ***Information Disclosure Statement***

3. Information Disclosure Statement (second supplement) filed on 5/9/05 is acknowledged and a signed copy is attached to this Office action.

#### ***Claim Rejections - 35 USC § 112, first paragraph withdrawn***

4. In view of cancellation of claims and amendments to the claims, the rejections (written description and enablement) under 35 U.S.C. 112, first paragraph are withdrawn.

#### ***Claim Rejections - 35 USC 102 withdrawn***

5. In view of cancellation of claims and amendments to the claims, the rejection under 35 U.S.C. 102(b) as being anticipated Snyder et al 1992, EPO 537830 is withdrawn.

6. In view of cancellation of claims and amendments to the claims, the rejection under 35 U.S.C. 102(b) as being anticipated by Snyder et al 1991 EPO0439210 or EPO 0439211 or EPO0439212 is withdrawn.

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**Claim Rejections - 35 USC 102 maintained**

7. The rejection of claims 32-33 and 36- 37 under 35 U.S.C. 102(b) as being anticipated by Flemmig et al 1996(Clinical and Diagnostic Laboratory Immunology; 3, 678-681) is maintained as set forth in the previous office action.

Flemmig et al disclose an immunoblotting method for detecting the presence of *A. actinomycescomitans* antibody (see abstract and page 679, left column under SDS-PAGE and immunoblotting). The method comprises contacting membrane proteins from *A. actinomycescomitans* that were separated by gel-electrophoresis (SDS-PAGE) with sera from infected individuals and thus read on contacting a test sample with a polypeptide of the claimed invention. After washing, the strips were incubated with goat anti-human IgA or IgG or IgM conjugated with alkaline phosphatase. The presence of a band is considered positive because the antigen present on the strip bound to an antibody present in a test sample and forms an immunocomplex that is positively identified by goat anti-human IgA or IgG or IgM conjugated with alkaline phosphatase. The positive band indicates the presence of *A. actinomycescomitans* in a test sample (page 679, left column under SDS-PAGE and immunoblotting and figure 1). The disclosed outer membrane protein inherently contain claimed SEQ.ID.NO: 52 because the outer-membrane proteins were obtained from cell lysates that contain mixture of polypeptides. Therefore, the prior art anticipates the claimed invention. In the absence of evidence to the contrary the disclosed prior art reads on the claimed invention since the OMP proteins bind to the specific anti-OMP antibodies. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

8. The rejection of claims 32-33 and 36- 37 under 35 U.S.C. 102(b) as being anticipated by Ebersole et al is maintained as set forth in the previous office action.

Ebersole et al disclose an immunoblotting method for detecting the presence of *A. actinomycescomitans* antibody (see abstract and page 659, right column under Western immunoblotting). The method comprises contacting outer membrane proteins from *A. actinomycescomitans* that were separated by gel-electrophoresis (figure1)) with sera from infected individuals and thus read on contacting a test sample with a polypeptide of the claimed invention. After washing the strips were incubated with goat anti-human IgA or IgG or IgM conjugated with alkaline phosphatase. The presence of a band is considered positive because the antigen present on the strip bound to antibody present in a test sample and forms an immunocomplex, which is positively identified by goat anti-human IgA or IgG or IgM conjugated with alkaline phosphatase. The positive band indicates the presence of *A. actinomycescomitans* in a test sample (page 660, left column under SDS-PAGE and immunoblotting and figure 2). The disclosed outer membrane proteins (OMP) contain the claimed peptide comprising at least SEQ.ID.NO: 52 because the outer-membrane proteins were obtained from cell lysates containing mixture of polypeptides including peptide comprising at least SEQ.ID.NO: 52. Therefore, the prior art anticipates the claimed invention. In the

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absence of evidence to the contrary the disclosed prior art reads on the claimed invention since the OMP proteins bind to the specific anti-OMP antibodies.

Applicants' arguments filed on 5/9/05 have been fully considered but they are not deemed to be persuasive.

Applicant states that the examiner failed to bear the burden of presenting at least a prima facie case of anticipation because SEQ ID NO: 52 is made by IVIAT technology and the art teaches in vitro grown OMP/OMA antigen, cites case laws of record and also submitted the Declaration by Dr. Handfield. Further, applicant states that neither of the arts, however, can teach or suggest the claimed polypeptide, SEQ NO: 52 because the art teaches the use of OMAS that are expressed in vitro (and possibly expressed both in vitro and in vivo) whereas polypeptide of SEQ ID NO: 52 was identified using IVIAT methodology and is therefore expressed only in vivo and would not be present in the in vitro grown cultures of Flemmig et al or Ebersol et al. Therefore, Flemmig et al or Ebersole et al do not anticipate the subject matter of claims 32, 33, 36, 37.

The examiner disagrees with the applicant because the examiner established a reasonable rejection based on the broadly claimed invention. The claims are drawn to a method of detecting the presence or absence of *A.actinomycescomitans* antibody in a test sample using an antigen "comprising" or "consisting essentially of" SEQ.ID.NO: 52 and are rejected correctly over a method of detecting the presence or absence of *A.actinomycescomitans* antibody using antigen comprising OMPS disclosed by Flemmig et al or Ebersol et al. Please note<sup>that</sup> the claims are not drawn to a method for detecting an antibody that specifically binds to the amino acid sequence SEQ.ID.NO: 52. Therefore, for the reasons of record now and as discussed in the previous Office action, the rejection is appropriate. Please note the examiner did not reject the claims 30-31 and 40-41. However, the claims 32-33 and 36-37 are drawn to

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methods of detecting antibodies present in the sample using immunogenic polypeptide comprising /consisting essentially of SEQ.ID.NO: 52. However, applicant is not claiming an isolated polypeptide comprising the amino acid sequence, SEQ.ID.NO: 52 but claiming a method for detecting the presence or absence of antibody. These antibodies are produced during in vivo infection and OMPS have positively identified the presence or absence of infection. The examiner acknowledges the Declaration provided by the inventor and understands that IVIAT is a great technology for identifying antigens that are important for understanding the immunological events leading to pathogenesis and appreciates the inventor's contributions. However, The Declaration does not provide any evidence that the prior art method does not identify the presence or absence of antibody produced during infection using outer membrane protein and is expected to bind to only SEQ.ID.NO: 52 made by "IVIAT" technology. In addition the claimed invention is drawn to a method of detecting the presence or absence A.actinomycetemcomitans antibody in a test sample and said antibody is produced during the infection to either outer membrane proteins or secreted proteins. Therefore, the argument that the presently claimed proteins are obtained by IVIAT methodology, neither of the arts, however, can teach nor suggest the claimed polypeptide, SEQ N0: 52 is not appropriate or correct in the absence of evidence to the contrary for the claimed invention.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claim 41 recites the limitation "antigen " in line 2. There is insufficient antecedent basis for this limitation in the claim.

**Remarks**

11. Claim 30-31 and 40 are allowed.
- Claims 32-33 and 36-37 and 41 are rejected.

**Conclusion**

12. This application contains claims 1-14 and 17-27 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

13 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

14. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number is 571-273-8300.

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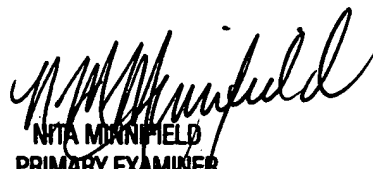
15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D



NTA MINNIFIELD  
PRIMARY EXAMINER  
7/26/05